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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,838	07/20/2001	Andrei W. Konradi	002010-678	8810

7590

09/18/2002

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EXAMINER

KIFLE, BRUCK

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 09/18/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/909,838

Applicant(s)

Konradi et al.

Examiner

Bruck Kifle, Ph.D.

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1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 8, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

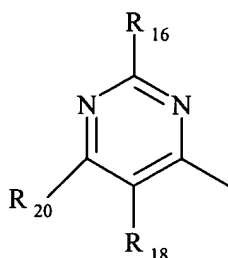
## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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***Election/Restriction***

Applicant's election without traverse of the pyrimidinyl ring system depicted below in Paper No. 9 is acknowledged.



Subject matter not embraced by this ring system is withdrawn from consideration as being drawn to non-elected subject matter.

***Improper Markush Rejection***

Claims 1-26 are rejected under a judicially created doctrine as being drawn to an improper Markush group, that is, the claims lack unity of invention. Ring A is defined in such a way that it keeps changing the core of the compound that determines the classification. By changing the value of "A", several patentably distinct and independent compounds are claimed. In order to have unity of invention the compounds must have "a community of chemical or physical characteristics" which justify their inclusion in a common group, and that such inclusion is not repugnant to principles of scientific classification" In re JONES (CCPA) 74 USPQ 149 (see footnote 2). The structural formula (I) does not have a significant structural feature that is shared by all of its alternatives which is inventive. Formula (I)A only has the -N-CH(R<sup>2a</sup>)-C-C(O)- fragment as common. Compounds embraced by formula (I) are so diverse in nature that a prior art anticipating a claim with respect to one member under 35 USC 102 would not render

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obvious the same claim under 35 USC 103. This is evidentiary of patentably distinct and independent inventions.

Limiting the claims to compounds wherein ring A is the elected ring system (the pyrimidinyl ring) would overcome this rejection.

***Claim Rejections - 35 USC § 112***

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- i) The terms substituted alkyl, substituted alkenyl, substituted alkynyl, substituted cycloalkenyl, etc. are indefinite because one cannot tell which substituents are intended and which ones are not.
- ii) The terms heteroaryl and heterocyclic are indefinite because one cannot say which heteroatoms are present, how many heteroatoms are intended, what size ring is intended and how many rings are present. In the case of heterocyclic it is unclear whether a fully saturated ring is intended or not.
- iii) In claim 1, last phrase should be rewritten in proper Markush language as alternatives as, for example, "or enantiomers, diastereomers or pharmaceutical acceptable salts thereof."
- iv) It is unclear which compound of formula I has a binding affinity to VLA-4 as expressed by an  $IC_{50}$  of about 15 $\mu$ M or less and which does not. It is unclear what the metes and bounds of "about" is.

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v) It is unclear in claim 24 which disease is mediated by VLA-4 and which one is not. How can one skilled in the art say for sure whether a given disease is mediated by VLA-4 or not?

vi) It is unclear what is intended to be accomplished in claim 26 and what the "biological sample" is.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

September 16, 2002

  
**Bruck Kifle**  
**Primary Examiner**  
**Art Unit 1624**